## Remarks

Amendments to the Claims and Specification

None of the amendments to the claims and specification adds new matter. The only amendments to the specification are to indicate trademarks and to correct obvious spelling errors. Support for the claim amendments are provided in the discussions below.

Objections to the Specification

The Office Action notes that:

(a) trademarks should be capitalized; and

(b) the specification should be amended to include essential material which is incorporated by reference if that material is required to overcome an objection, rejection, or other requirement imposed by the office.

The specification is amended to capitalize trademarks. The specification has not been amended to include material incorporated by reference, as none of the incorporated material is required to address any of the objections or rejections in this Office Action.

Please withdraw the objections.

Rejection Under 35 U.S.C. § 101

Claims 1-15 are rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter. Claim 1 has been amended as the Office Action suggests to clarify that the recited antigens are "isolated." Please withdraw the rejection.

Rejections Under 35 U.S.C. § 112 ¶ 2

Claims 1-4, 7-15, and 18-23 are rejected under 35 U.S.C. § 112 ¶ 2 as indefinite. Each of items (a) – (o) under this rejection is addressed separately below.

(a) Independent claim 1 is amended to recite "Group B streptococcus (GBS)." The specification supports this amendment on page 1, lines 13-14.

(b) Claim 2 is rejected as indefinite because the recitation "serogroup II" allegedly is unclear in view of the recitation in claim 1 of "serotype." Claim 2 is amended to recite "serotype."

(c) Claim 1 is amended to delete the recitation of "a combination of at least two polypeptide or fragments thereof."

(d) Claim 1 is amended to recite "selected from the group consisting of," rather than "selected from the antigen group consisting of."

(e) The recitation "as represented by" in claims 1, 3, 4, 8, 9, and 18 allegedly is unclear. To advance prosecution Applicants have amended these claims to recite "set forth as" as suggested in the Office Action.

(f) and (g) The recitation "fragments thereof" in claims 1 and 4 and "fragment thereof" in claims 2 and 3 allegedly is unclear. Claim 1 is amended to recite "immunogenic fragments of GBS . . . comprising at least 7 consecutive amino acids." The specification supports this amendment on page 4, lines 4-6.

(h) and (i) The terms "saccharide antigen," "saccharide," "polypeptide antigens," and "polypeptide" in claim 1 and the terms "GBS saccharide antigen" and "saccharide" in claim 19 allegedly are confusing. Claim 1 as amended recites a "GBS saccharide antigen" and "GBS

polypeptide antigens." Claim 19 as amended recites that "the GBS saccharide antigen comprises a GBS serotype Ia saccharide antigen."

(j) Claims 1, 2, and 3 are allegedly unclear because the term "said GBS polypeptide antigens" lacks antecedent basis. As amended, claims 1, 2, and 3 no longer contain this recitation.

(k) Dependent claim 4 is allegedly broader than claims 1 and 3 on which it depends, because the term "GBS antigens" in claim 4 is broader than the term "GBS polypeptide antigens" in claim 1. As amended, claim 4 no longer recites "GBS antigens."

(l) Claim 10 allegedly lacks antecedent basis for the term "at least one GBS polypeptide antigen." Claim 10 is amended as the Office Action suggests to recite "at least one of the GBS polypeptide antigens."

(m) The spelling of "*N. meningitidis*" and "pertussis" is corrected in claim 12.

(n) Dependent claim 18 allegedly lacks antecedent basis for the term "the two GBS polypeptide antigens." Claim 18 is amended to recite "the at least two GBS polypeptide antigens," for which claim 1 provides antecedent basis.

(o) Claims 2-4, 7-15, and 18-23 are rejected as indefinite because they depend from claim 1. Claim 1 as amended is definite, which moots this rejection of its dependent claims.

Please withdraw the rejection.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-4 and 10-13 are rejected as anticipated by Paoletti (*Infect. Immun. 62*, 3236-43, 1994) under 35 U.S.C. § 102(b). Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The rejection is based on the Office Action's interpretation of the recitation "fragment thereof" as encompassing a single amino acid residue. Claim 1 as amended recites fragments comprising "at least seven consecutive amino acids" of the recited amino acid sequences. Paoletti does not disclose this subject matter. Please withdraw the rejection.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-4, 10-15, and 18-23 are rejected under 35 U.S.C. § 103(a) as obvious over WO 02/34771 in view of Wessels (*Inf. Immun. 61*, 4760-66, 1993). Applicants respectfully traverse the rejection.

> Section 103(a) of 35 U.S.C. states:
>
> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Obviousness under 35 U.S.C. § 103(a) is a question of law based on several factual inquiries:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at

> issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.

*Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). In *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 407 (2007), the Supreme Court explained, "While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls."

The U.S. Patent and Trademark Office bears the initial burden of establishing a *prima facie* case of obviousness based on the results of the factual inquiries under *Graham*. M.P.E.P., 8th ed., § 2142. The Office Action cites the secondary reference, Wessels, as disclosing a vaccine comprising type Ia GBS capsular polysaccharide conjugated to tetanus toxoid. The Office Action asserts it would have been obvious to combine the teaching of Wessels with that of WO 02/34771 to arrive at the claimed compositions, which comprise an isolated GBS saccharide antigen and at least two specified GBS polypeptide antigens.

The Office Action cites "claim 28; lines 9-10 of page 9; pages 7, 8, 2997 and 2992" of WO 02/34771 as disclosing

> a composition comprising two or more GBS proteins or sequences comprising GBS 80 and GBS 322 proteins having SEQ ID NO: 8780 (i.e., the instantly recited SEQ ID NO: 2) and SEQID [sic] NO: 8540 (i.e., the instantly recited SEQ ID NO: 322), or fragments thereof.

The cited portions of WO 02/34771 do not disclose such compositions. Claim 28 of WO 02/34771 is directed to "a composition comprising two or more proteins, wherein each protein is a protein according to claim 1, claim 2 or claim 3." Each of claims 1, 2, and 3 recites almost 5,500 proteins. This is not a disclosure of any of pairs of antigens specified in pending claims 1-4, 10-15, and 18-23.

Lines 9-10 of page 9 state: "the invention also provides compositions comprising two or more proteins of the present invention. The two or more proteins may comprise GBS sequences or may comprise GAS and GBS sequences." Again, there is no disclosure of any of the antigens recited in the pending claims.

Pages 7-8 describe compositions comprising "a protein or [sic; of] the invention" and one or more of a list of antigens which are not GBS proteins. Pages 7-8 do not describe any compositions comprising the specified GBS antigens.

Pages 2992 and 2997 are pages of a table (Table IV) that lists GBS proteins and their corresponding sequence identifiers. GBS 80 is listed on page 2992, together with 117 other GBS proteins. GBS 322 is listed on page 2997 together with 55 other GBS proteins. Altogether, Table IV lists many hundreds of GBS proteins. There is no suggestion in Table IV to make any particular combination of the listed antigens.

Neither the cited portions nor any other part of WO 02/34771 provides a teaching or suggestion of a composition comprising the combinations of antigens recited in the pending claims. It remains black letter law that obviousness requires at least a suggestion of all of the features in a claim. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). *See also* M.P.E.P. § 2141(III):

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

> Exemplary rationales that may support a conclusion of obviousness include:
>
> * * *
>
> (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

Over 15,000,000 pairs of GBS antigens are possible from the GBS antigens disclosed in WO 02/34771.[1] This is not "a finite number of identified, predictable solutions" which might support a *prima facie* case that any of claims 1-4, 10-15, and 18-23 are obvious. Even if, *arguendo*, one of ordinary skill in the art would have combined the teachings of WO 02/34771 and Wessels, the Office Action does not articulate a reason why any teachings in WO 02/34771 would have motivated one of ordinary skill in the art to select any of the particular combinations of GBS antigens recited in the pending claims.

The Office Action has not made a *prima facie* case that claims 1-4, 10-15, and 18-23 are obvious. Please withdraw the rejection.

Objection to the Claims

The Office Action objects to claims 1, 3, 4, 8, 9, and 18 "for not leaving a space after the limitation 'SEQ ID NO:'." Office Action at page 12. The sequence listing rules are set forth in 37 C.F.R. §§ 1.821 – 1.825 and discussed in M.P.E.P. §§ 2420 – 2435. There is no requirement in either authority for a space after "SEQ ID NO:." In fact, in each example given, there is no space after "SEQ ID NO:." For example:

[1] $\frac{5,500 \times (5500 - 1)}{2}$

| | |
|---|---|
| 37 C.F.R. § 1.821(d) | (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. |
| M.P.E.P. § 2422.02 | ing figures. It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. |
| M.P.E.P. § 2422.03 | would be treated as noted herein by the Office. With respect to "conservatively modified variants thereof" of a sequence, the sequences may be described as SEQ ID NO:X and "conservatively modified variants thereof," if desired. With respect to a sequence that "may be deleted at the C-terminus by 1, 2, 3, 4, or 5<br><br>claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 343 of SEQ ID NO:25" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embed-<br><br>35 U.S.C. 112, first or second paragraphs The use of sequence identification numbers (SEQ ID NO:X) only provides a shorthand way for applicants to discuss and claim their inventions. These identification numbers do not in any way restrict the manner in which an invention can be claimed. |
| 37 C.F.R. § 1.823(b) | <210> SEQ ID NO:#:... ..... Response shall be an integer representing the SEQ ID NO shown. M. |

The claims as written are proper. Please withdraw the objection.

Respectfully submitted,

**BANNER & WITCOFF, LTD.**

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